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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,266	04/05/2001	James G. Skakoon	50741-000005/US/01	4355
27572 7590 01/10/2008 HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER LAURITZEN, AMANDA L	
			ART UNIT 3737	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/827,266

Applicant(s)

SKAKOON ET AL.

Examiner

A. Lauritzen

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10-12,17-21,23,24,27,28 and 33-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10-12,17-21,23,24,27,28 and 33-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 30 Oct 2007; 14 Nov 2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-8, 10-12, 33-38 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 and others have been amended to specify a *handheld* advancer assembly, but this feature is not expressly supported by the specification, nor can it reasonably be inferred. Claims 35-37 further cites a “pistol” grip configuration which is not supported by applicant’s specification.

Examiner notes that, additionally, at least claim 46 recites unsupported subject matter in the way of a handheld pistol grip, none of these words being supported or ideas inferred from applicant’s disclosure of the invention.

Response to Arguments

Applicant's arguments filed 12 October 2007 have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection. Applicant has asserted that the claimed invention distinguishes from the cited art in that the advancer assembly is handheld; Examiner disagrees. While the Taylor unit includes components that will occupy a sizeable amount of space, the actual advancer assembly – that is, the thumb wheel portion of the unit – is

operated by hand and therefore handheld. This component, like the claims, is remote from the guide unit.

Regarding claims 17 and 24, the thumb wheel unit (either that which accomplishes coarse or fine adjustments), constitutes the "rotating wheel advancer" of claim 17 and the "adjusting wheel system" of claim 24. This thumb wheel adjustment utilizes rotational movement by the operator's hands to translate the instrument linearly, as claimed. This system(s) constitute a "trajectory guide device" in that it is capable of moving a surgical instrument through an exactly defined trajectory (col. 1, ll. 35-37 of Taylor et al. '629).

Regarding obviousness of an MR-compatible cable, it is known within the art to utilize surgical instrument guidance systems, and a pulley system that makes use of cable(s) is understood to be a standard means for positioning and/or orienting the surgical tool. Further, it is also well known to skilled artisans to guide surgical procedures (i.e., imaging taking place inter-operatively) by a magnetic resonance imaging system, in which case MR-compatibility would be necessary. It was previously pointed out that the difference of providing an MR-compatible cable or not was obvious in the provisional double patenting rejection presented 27 February 2006, which cited a difference in the claims "in only the obvious variation of introducing an MR-compatible cable...". This statement was not contested and the pertinent claims of the instant application were amended to overcome the rejection.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 2, 4-8, 10-12, 17-21, 23-24, 27, 33-38 and 39-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. 5,950,629) in view of Truwit (US 2002/0019641).

Taylor et al. disclose all features of the invention as substantially claimed including a calibrated introducer device for guiding surgical instruments during a procedure, the apparatus specific to a guide unit and hand-guided advancer assembly that is operated by rotating a thumb wheel advancer to produce a linear range of motion at the site of the surgical tool (see fine motion manipulator [14] of Fig. 1A with linear motion section [68]; also col. 8, ll. 35-36); a holder assembly traveling along the range of motion of the guide unit capable of receiving attachment of a medical tool (member [115] acts to hold the surgical tool through clamp [117] having an implied hole or opening; also col. 11, ll. 34-36); a thumb wheel and/Or rotating wheel advancer that translates rotation by the user about a thumb wheel axis into motion of the holder assembly (fine motion manipulator [14] is interpreted as the thumb wheel advancer when operated manually, as in col. 7, ll. 3-5). The apparatus of Taylor et al. further includes an indicator scale coupled to the thumb wheel that indicates the position of the holder assembly with a frameless locating attachment including a plurality of IR reflective spheres and/or IR

generated LED devices and IR sensitive camera(s) (beacons [112] enable position determination as in col. 11, line 66 – col. 12, line 6; beacons contain LED devices or reflectors as in col. 11, lines 43-47).

Taylor '629 further discloses a centering plate comprising at least two walls partially defining an opening in the plate wherein the centering plate can be adjusted to center the primary medical device (col. 10, lines 3-45 in which roll, pitch and yaw sections comprise plates 96 and 98 to provide orthogonally decoupled motions about the center point to position the medical instrument). Taylor also discloses a means for selectively locking and unlocking movement in col. 3, lines 48-49, which implies the locking device must be actuated before motion of holder assembly is permitted. The locking device of Taylor '629 is further capable of being selectively actuated in either a freewheeling mode or a discrete step mode (i.e., the locking device is freewheeling when motion is enabled in all degrees of freedom and discrete when locks are actuated for aligning select degrees of freedom as in col. 14, lines 9-28; refer also to col. 3, lines 63-67 for discrete locking in either locked or unlocked fashion).

Taylor et al. '629 further discloses a local position sensor that includes an encoder that is mounted to the guide unit that includes a remote user interface for display to the surgeon (col. 15, lines 22-26; col. 11, lines 62-66).

Taylor et al. cite trajectory guide systems such as that of patent '629 being capable of moving a surgical instrument through an exactly defined trajectory (co. 1, lines 35-37).

The disclosure of Taylor et al. is not specific to a locking mechanism that is activated by hand, a remote user interface, or an MR-compatible cable/pulley system to accomplish displacement of the surgical tool, but in the same field of endeavor, Truwit discloses a robotic

surgical instrument guidance system for use with MR-guided procedures that includes a locking mechanism and remote user interface (abstract; [0011]; [0019]-[0020]). It would have been obvious to provide a hand locking mechanism and alternatively provide a cable system as an actuating mechanism, as taught by Truwit, for the purpose of making the actuating units more compact while providing precise user-control.

Regarding claim 24, the locking mechanism(s) of Truwit and/or Taylor et al. are regarded as "fixation members". Further, any portion of the system which acts to hold the assembly in place with respect to the patient functions as a fixation member.

Regarding claim 34, the cable assembly must necessarily be attached at a first side of the advancer and a second side (two attach points), with a wheel moveable in at least one of two directions in order for the wheel to be operatively affected by the cable and actuated to translate the medical tool along a desired trajectory.

2. Claims 19 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor '629 in view of Truwit '641 and Stark et al. (U.S. 5,823,975).

The invention of Taylor as modified by the teachings of Truwit includes all features of the instant invention as substantially claimed, but is not specific to use of a potentiometer to sense position with a device mounted coil; however, Stark et al. teach using a potentiometer with a device mounted coil to solve the same problem of position determination (col. 6, line 67 and col. 7, line 1). It would have been obvious to use a potentiometer and a spring for the purpose of position sensing as taught by Stark in order to monitor component displacement as a function of a change in output resistance (at Stark col. 7, lines 62-66).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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1/7/2008

